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Najishadh N. Desai	\$0,630
Name of Attorney/Agent	Registration No.
	
Signature of Attorney or Agent	

P&G Case 8448R

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :  
Robert Joseph Isfort et al. :  
Serial No. 10/649,852 :  
Filed 8/27/2003 :  
For: Methods For Identifying Compounds For Regulating Muscle Mass Or Function  
Using Corticotropin Releasing Factor Receptors

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made on the attached Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☐ 37 C.F.R. §1.97(b)(1) - U.S. Direct (use when filing IDS with nonprovisional patent application, or with Request for Continued Examination (RCE); or within 3 months of filing a nonprovisional patent application)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(1), is being filed with the patent application, with a Request for Continued Examination or within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☒ **37 C.F.R. §1.97(b)(3) - (use when filing IDS more than 3 months after filing a nonprovisional patent application, but prior to receipt of first Office Action)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

3. ☐ **37 C.F.R. §1.97(b)(4) - (use when filing IDS prior to receipt of first Office Action after the filing of a Request for Continued Examination (RCE) under §1.114)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(4). Applicants have not received a first Office Action after filing a Request For Continued Examination (RCE). Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

4. ☐ **37 C.F.R. §1.97(c) with fee payment - (use when filing IDS after receipt of first Office Action, and before receipt of Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

5. ☐ **Information to be Considered with Continued Prosecution Application (CPA) Filing (use when filing IDS with a Continued Prosecution Application (CPA) for Design Case).** This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 C.F.R. 1.53(d).

**ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:**

☐ (1) (For use with applications filed prior to or on June 30, 2003.) Copies of the cited documents are enclosed.

OR

☒ (2) (For use with applications filed after June 30, 2003.) In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

OR

☐ (3) All of the cited references were previously cited by or submitted to the USPTO in prior application Case No. \_\_\_\_, U.S. Patent Application Serial No. \_\_, filed \_\_. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

OR


☒ (4) Copies of all said documents, except Cite Numbers 1 - 27, were submitted and considered in parent application U.S. Patent Application Serial No. 09/799,978, filed 03/06/2001; U.S. Patent No. 6,670,140, issued 12/30/2003. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of references not previously submitted are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (5) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

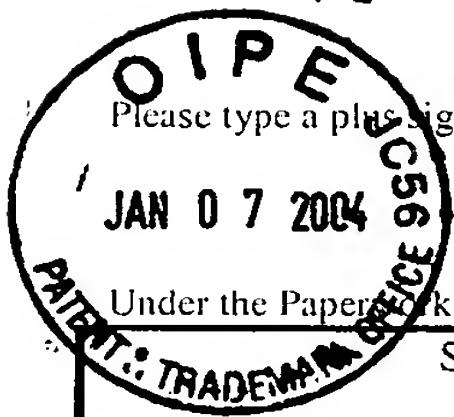
☐ (6) Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

☐ Additional information is attached.

Respectfully submitted,

By   
 Naishadh N. Desai  
 Attorney or Agent for Applicant(s)  
 Registration No. 50,630  
 (513)622-0087

Date: January 5, 2004  
**Customer No. 27752**  
 (IDS.doc) (Last Revised 10/10/03)



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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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SHEET 1 of 3

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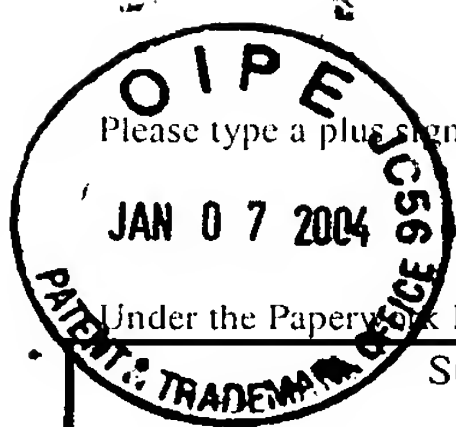
Application Number	10/649,852
Confirmation Number	7224
Filing Date	August 27, 2003
First Named Inventor	Robert J. Isfort
Group Art Unit	
Examiner Name	
Attorney Docket Number	8448R

**U. S. PATENT DOCUMENTS**

EXAMINER INITIALS*	Cite No. <sup>1</sup>	U.S. PATENT DOCUMENT		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	5,844,074	Kind Code <sup>2</sup> (if known)	Rivier	12/01/1998	
	2	5,663,292		Rivier	09/02/1997	
	3	5,235,036		Kornreich, et al.	09/10/1993	
	4	5,869,450		Wei, et al.	02/09/1999	
	5	5,824,771		Rivier	10/20/1998	

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIALS*	Cite No. <sup>1</sup>	FOREIGN PATENT DOCUMENT			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	6	WO	97/00063	Kind Code <sup>5</sup> (if known)	Vale, et al.	01/03/1997		
	7	EP	0 860 501	A2	Lovenberg, et al.	08/26/1998		
	8	WO	96/37223	A1	Grabstein, et al.	11/28/1996		



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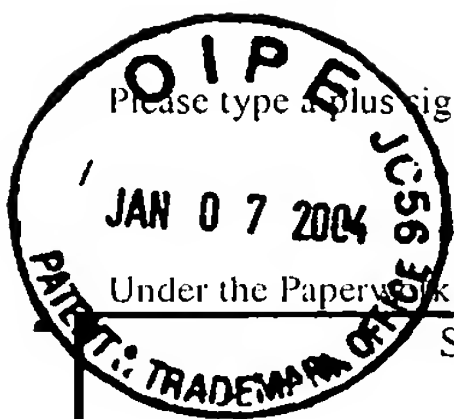
SHEET 2 of 3

### COMPLETE IF KNOWN

Application Number	10/649,852
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First Named Inventor	Robert J. Isfort
Group Art Unit	
Examiner Name	
Attorney Docket Number	8448R

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
	9	T.M. REYES, ET AL., "Urocortin II: A member of the corticotropin-releasing factor (CRF) neuropeptide family that is selectively bound by type 2 CRF receptors", <i>PNAS</i> , February 27, 2001, 2843-2848, Vol. 98, No. 5, USA.	
	10	E.B DE SOUZA, "Corticotropin-Releasing Factor Receptors: Physiology, Pharmacology, Biochemistry and Role In Central Nervous System and Immune Disorders", <i>Psychoneuroendocrinology</i> , 1995, 789-819, Vol. 20, No. 8, Elsevier Science Ltd., USA.	
	11	D.T. CHALMERS, ET AL., "Corticotropin-releasing factor receptors: from molecular biology to drug design", <i>TIPS</i> , April 1996, 166-172, Vol. 17, Elsevier Science Ltd., USA	
	12	H.A. THOMAS, ET AL., "CRF and Related Peptides as Anti-Inflammatory Agonists", <i>Annals New York Academy of Sciences</i> , 219-228.	
	13	E.T. WEI, ET AL., "Peripheral anti-inflammatory actions of corticotropin-releasing factor", <i>Ciba Foundation Symposium 172</i> , 1993, 258-276, Wiley, Chichester.	
	14	J.R. MCCARTHY, ET AL., "Recent Advances with the CRF <sub>1</sub> Receptor: Design of Small Molecule Inhibitors, Receptor Subtypes and Clinical Indications", <i>Current Pharmaceutical Design</i> , 1999, 289-315, Vol. 5, Bentham Science Publishers B.V.	
	15	J.R. MCCARTHY, ET AL., "Chapter 2. Recent Progress in Corticotropin-Releasing Factor Receptor Agents", <i>Annual Reports in Medicinal Chemistry</i> , 11-20, Vol. 34, Academic Press.	
	16	G.P. CHROUSOS, ET AL., "Corticotropin Releasing Factor: Basic Studies and Clinical Applications", <i>Prog. Neuro-Psychopharmacol. &amp; Biol. Psychiat.</i> , 1985, 349-359, Vol. 9, Pergamon Press Ltd., Great Britain.	
	17	G.B. CUTLER, JR., M.D., "Corticotropin-Releasing Hormone (CRH): Clinical Studies and Use", <i>The Endocrinologist</i> , 1997, 10S-16S, Vol. 7, No. 1, Suppl. 1, Williams & Wilkins.	
	18	M.J. OWENS, ET AL., "Physiology and Pharmacology of Corticotropin-releasing Factor", <i>Pharmacological Reviews</i> , 1991, 425-473, Vol. 43, No. 4, The American Society for Pharmacology and Experimental Therapeutics, USA.	
	19	L. ARBORELIUS, ET AL., "The role of corticotropin-releasing factor in depression and anxiety disorders", <i>Journal of Endocrinology</i> , 1999, 1-12, Vol. 160, Society for Endocrinology, Great Britain.	
	20	D.N. ORTH, "Corticotropin-Releasing Hormone in Humans", <i>Endocrine Reviews</i> , 1992, 164-191, Vol. 13, No. 2, The Endocrine Society, USA.	
	21	E. EMERIC-SAUVAL, "Corticotropin-Releasing Factor (CRF) - A Review", <i>Psychoneuroendocrinology</i> , 1985, 277-294, Vol. 11, No. 3, Pergamon Journals Ltd., Great Britain.	
	22	J. SPIESS, ET AL., "Molecular Properties of the CRF Receptor", <i>TEM</i> , 1998, 140-145, Vol. 9, No. 4, Elsevier Science Ltd.	
	23	K.D. DIETERICH, ET AL., "Corticotropin-releasing factor receptors: An overview", <i>Exp. Clin. Endocrinol. Diabetes</i> , 1997, 65-82, Vol. 105, Johann Ambrosius Barth.	
	24	P.J. GILLIGAN, ET AL., "Corticotropin Releasing Factor (CRF) Receptor Modulators: Progress and Opportunities for New Therapeutic Agents", <i>Journal of Medicinal Chemistry</i> , May 4, 2000, 1641-1660, Vol. 43, No. 9, American Chemical Society.	
	25	C.A. MALTIN, ET AL., "Clenbuterol, a $\beta$ -adrenoceptor agonist, increases relative muscle strength in orthopaedic patients", <i>Clinical Science</i> , 1993, 651-654, Vol. 84.	



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SHEET 3 of 3

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Attorney Docket Number	8448R

	26	J.F. SIGNORILE, ET AL., "Increased Muscle Strength in Paralyzed Patients after Spinal Cord Injury: Effect of Beta-2 Adrenergic Agonist", <i>Arch Phys Med Rehabil</i> , 1995, 55-58, Vol. 76.	
	27	L. MARTINEAU, ET AL., "Salbutamol, a $\beta_2$ -adrenoceptor agonist, increases skeletal muscle strength in young men", <i>Clinical Science</i> , 1992, 615-621, Vol. 83.	
	28	MEDLER, S., "Comparative trends in shortening velocity and force production in skeletal muscles", <i>Am. J. Physiol Regulatory Integrative Comp Physiol</i> , 2002, Vol. 283, pp. R368-R378.	
	29	ROME, L.C., "The Design of Vertebrate Muscular Systems: Comparative and Integrative Approaches", <i>Clinical Orthopaedics and Related Research</i> , 2002, No. 403S, pp. S59-S76.	

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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